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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,188	03/29/2001	John Greeven	10004662-1	1218

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EXAMINER	
SHAPIRO, JEFFERY A	

ART UNIT	PAPER NUMBER
3653	

DATE MAILED: 01/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/823,188	GREEVEN ET AL.	
	Examiner	Art Unit	
	Jeffrey A. Shapiro	3653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,25-30,32 and 53-64* is/are pending in the application.

4a) Of the above claim(s) *50-52,65 and 66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,25-30,32 and 53-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, directed towards Claims 22, 25-30, 32 and 53-64 in the reply filed on 10/17/05 is acknowledged.

Claims 50-52, 65 and 66 will be withdrawn. Note that Claims 50-52 depend from Independent Claim 65 and were not included in the original Group II designation. During a teleconference on 1/5/06, Attorney Donald J. Coulman agreed to the withdrawal of Claims 50-52 as well as 65 and 66 from prosecution.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 22, 25-30, 32-39, 53-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liff (US 6,471,089 B2) in view of Boyer (US 6,202,923 B1).

Liff discloses the drug dispensing system as described in Claims 22, 32, 36, 53 and 54, including a controller (314), a reservoir of pharmaceutical (20) **specific to an individual and** to be dispensed over time to a patient, the pharmaceutical including at least one of tablets, liquids or gases, to be administered to a patient in individual or discrete doses according to a treatment regimen. See col. 1, last line and col. 2, lines 1-7 that mentions "dispensing a pharmaceutical over time" and col. 8, lines 16-20 for

liquid and other forms of drugs being dispensed. See also col. 2, lines 52-54 which indicate that each bottle contains a certain number of doses, which can be construed as including one dose or a several doses. Note that the reservoir can be construed as being specific to an individual, such as a doctor in a hospital or nurse, who can either administer/manage the dispensing or who might outright own the dispenser. Note also that an individual may be construed to be an institution such as a pharmacy, research center or a hospital.

Liff further discloses a drug delivery mechanism ***located proximate to the patient at a location remote to a hospital.*** ***S***ee figures 5-6c. Note that the drug delivery mechanism may be construed to be located proximate to a patient **in** a hospital if that patient's room is located across from the dispenser for the entire hospital. Note also that locating such a dispenser **in** all hospital rooms could be construed to be no different than locating them across the hall or down the hall, at the other end of the floor. The limitations "proximate to the patient remote to a hospital" can be construed in a reasonably broad sense to even include locating a dispenser, such as Liff's element (20), at a bedside of a patient located **at their home**. If the home is located next door to the hospital, it can be construed as remote from the hospital. Note further, that such limitations as "***located proximate to the patient at a location remote to a hospital*** " are seen as arbitrary to the function of the system, and that for all practical purposes, Applicant's claimed system functions as Liff's system does.

Note also that it would have been obvious to one ordinarily skill in the art to have made the reservoir any particular size so as to hold the amount of pharmaceutical

required to meet the needs of the patient. Regardless of the size of the reservoir, Liff's system functions the same as Applicant's system with the same structure.

Liff also discloses a data network interface coupled to said controller, as illustrated in figure 13a.

Liff also discloses, as described in Claims 31-34, 37, 38 and 39, sending messages to and from a health care service provider or drug supplier. See figure 14T, for example, noting payors, doctors, inventory and refills have files for information pertaining thereto.

Liff also discloses that said data message identifies the patient and the identity of the particular drug in figure 14K.

Liff discloses dispensing the pharmaceutical to the patient from the reservoir in a precise amount in response to signals from said controller, since the dispenser dispenses drugs in a wide variety of forms, such as bottles or containers of pills, based upon signals from a controller.

As described in Claims 25 and 55 Liff disloses a human/display interface *including at least one of a tactile input device or a speech recognition device operatively coupled to the controller.* See figures 14A-14T, and 16, noting that laptop computers (566) and workstation (555) inherently have, at the very least, either a keyboard or a touchscreen. Note also pen computers (558 and 568), which use a pen for input.

Liff further discloses, as described in Claims 26, 27, 35 and 58, effecting payment for the provision of health care service or for a drug. See col. 18, lines 4-17.

Liff discloses, as described in Claims 28 and 29, that a message is transported over the internet (see figure 18), and that a message is transported via wireless (see col. 8, line 24.

As described in Claims 30, 57, 59, 60, 62 and 63, Liff discloses a pharmaceutical level detector (182), as illustrated in figure 7c. The pharmaceutical level detector is configured to ascertain at least one of measured weight of pharmaceutical remaining in the reservoir, decremented amount remaining in the reservoir, depth of measurement of pharmaceutical in the reservoir, and static pressure within the reservoir, since the level detector (182) detects the level of the inventory remaining in a reservoir. Note that "the reservoir" can be reasonably broadly construed as being either a single dispensing device or several dispensing devices, and that such a level of inventory is construed as being a decremented amount, as the bottles of drugs are discrete items.

Liff discloses that the controller includes a memory device contained within the dispensing system. See Claim 30 of Liff et al, which states that a memory is connected to the system computer.

Liff discloses that the memory device contains at least one treatment regimen regulating dispensing of individual doses of pharmaceutical to the patient. See Claim 30 of Liff et al, which further states that the memory stores patient data and drug interaction data. See also col. 18, lines 42-65.

Liff does not expressly disclose, but Boyer discloses a reservoir (22) for releasing unpackaged doses of pharmaceutical (see col. 12, lines 5-30) to a patient configured to contain a plurality of individual doses of unpackaged pharmaceutical by responding to

signals from a controller (83) through a data network (82, 84), wherein the intelligent drug dispensing appliance (22) is sized and shaped for non-hospital placement proximate to the individual patient. Note that the term bedside suggests that the dosage releasing device can be placed at any bedside, for example, in a home or a hospital. Note also that one ordinarily skilled in the art would recognize that it would be practical to place the dispenser at a location where it is needed, of which the bedside of a patient is just such a place. Note also that the system of Liff and Boyer works the same as Applicant's system, whether or not it is located at the patient's bedside.

Both Liff and Boyer are analogous art because Liff discloses a hospital management system controlling drug dispensers for packaged doses of pharmaceutical and Boyer discloses a hospital management system controlling a drug dispenser for unpackaged doses of pharmaceutical.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have used Boyer's dispenser of unpackaged doses of pharmaceutical in the hospital management system of Liff.

The suggestion/motivation for doing so would have been to more efficiently monitor and track unpackaged pharmaceutical doses dispensed by said devices as well as to increase workflow and reduce errors. See Boyer, col. 4, lines 20-32. Note also Liff at col. 1, lines 43-49, which indicates that decentralized unit-based dispensing devices lowers costs relative to centrally located devices.

Regarding Claims 61 and 64, note that it would have been obvious to one of ordinary skill in the art to have detected static pressure in the reservoir, as static

pressure information is considered a functional equivalent of inventory level in determining how full the reservoir is. Since Liff at col. 8, lines 16-20 describes liquid and other forms of drugs being dispensed, it would have been obvious to one of ordinary skill in the art to have used the static pressure of the liquid pharmaceutical being dispensed in order to determine the volume amount of liquid remaining. Note also that Applicant's specification at p.5, lines 15-24 state that

> [o]ther methods by which the pharmaceutical within the reservoir can be determined would include, but not limited to: a measured weight of the reservoir (not shown); a depth measurement by way of an ultrasonic or mechanical transducer (not shown) or measured static pressure within the reservoir 104. The determination of pharmaceutical exhaustion is not germane to an understanding of the invention disclosed and claimed herein. Once a determination is made that more pharmaceutical is required, by using the method and apparatus disclosed hereinafter, obtaining a refill can be automated from either the drug delivery appliance, a medical service provider or a pharmaceutical provider."

Applicant seems to indicate that regardless of the method or device that senses the amount of material in the reservoir, an automatic refill can be generated. Applicant also does not state a reason for using one particular sensing device over the other. Therefore, Liff is considered to meet the limitations described in Claims 61 and 64.

4. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman (US 6,471,087 B1) in view of Boyer. Shusterman discloses Applicant's claimed system including, as described in Claim 53, a controller (800), illustrated in figure 8, a reservoir of pharmaceutical specific to the individual patient to be dispensed over time, as mentioned in col. 2, lines 23-36, and a drug dispensing mechanism (212), located proximate the patient at a location remote to a hospital, the drug delivery

mechanism coupled to, and responsive to, the controller and to the reservoir to dispense the pharmaceutical to the patient from the reservoir in a precise amount in response to signals from said controller. Again, note col. 2, lines 25-27, which indicates that a precise dose of medication is stored in each compartment for dispensing. Shusterman also discloses a data network interface (400) coupled to said controller. See col. 4, lines 10-14. See also figure 8, element (840), and col. 15, lines 15-20 of Shusterman that illustrates and describes a "dosing schedule" that defines dosing intervals (i.e., a prescription regimen) for a prescribed drug.

Shusterman does not expressly disclose, but Boyer discloses a reservoir (22) for releasing unpackaged doses of pharmaceutical (see col. 12, lines 5-30) to a patient configured to contain a plurality of individual doses of unpackaged pharmaceutical by responding to signals from a controller (83) through a data network (82, 84), wherein the intelligent drug dispensing appliance (22) is sized and shaped for non-hospital placement proximate to the individual patient. Note that the term bedside suggests that the dosage releasing device can be placed at any bedside, for example, in a home or a hospital.

Note also that one ordinarily skilled in the art would recognize that it would be practical to place the dispenser at a location where it is needed, of which the bedside of a patient is just such a place. Note also that the system of Shusterman and Boyer works the same as Applicant's system, whether or not it is located at the patient's bedside.

Both Shusterman and Boyer are analogous art because Shusterman discloses a central controller (100) system controlling drug dispensers for packaged doses of pharmaceutical and Boyer discloses a hospital management system controlling a drug dispenser for unpackaged doses of pharmaceutical. See Shusterman, figure 1 and col. 3, lines 65-67 and col. 4, lines 1-6.

Additionally, both Shusterman and Boyer are analogous art because Shusterman discloses a hospital management system controlling drug dispensers for packaged doses of pharmaceutical and Boyer discloses a hospital management system controlling a drug dispenser for unpackaged doses of pharmaceutical.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have used Boyer's dispenser of unpackaged doses of pharmaceutical in the hospital management system of Shusterman.

The suggestion/motivation for doing so would have been to more efficiently monitor and track unpackaged pharmaceutical doses dispensed by said devices as well as to increase workflow and reduce errors. See Boyer, col. 4, lines 20-32. Note also Shusterman at col. 1, lines 19-38, which indicates that the medical profession endeavors to reduce labor costs associated with large nursing staffs monitoring patients by using accurate devices which remotely monitor drug dosage dispensing devices, thereby allowing fewer staff to safely monitor more patients located at remote areas such as their home.

5. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liff et al in view of Boyer and further in view of Shusterman. Liff et al discloses the drug dispensing system as described above. Liff et al does not expressly disclose, but Shusterman discloses as described in Claim 56, at least one sensor (216, 218) operatively coupled to the controller, the sensor capable of providing data signals indicative of the patient's physical condition. See figures 4b, 5, 6, 7.

Both Liff and Shusterman are considered to be analogous art as they both concern medication dispensing and medical information systems.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to have interfaced Shusterman's remote patient monitoring garment with Liff's medical information system and therefore Liff's medication dispensing system.

The suggestion/motivation would have been to enhance the patient's medical history/profile and to automate data collection of the patient, since such information is important in diagnosing and treating medical problems with pharmaceuticals dispensed by Liff's dispensers. See Liff, figure 13e, noting element (336) designating a patient profile, which is used in determining pharmaceutical conflicts, for example. See also Liff at col. 19, lines 38-52, which further describes this. See also Shusterman, col. 1, lines 18-63, which mentions that patient monitoring is labor intensive.

Response to Arguments

6. Applicant's arguments with respect to Claims 22, 25-30, 32-39 and 53-64 have been considered but are moot in view of the new ground(s) of rejection.

Boyer provides teaching for individual tablet dispensers to be used to dispense bulk tablet pharmaceuticals. Boyer further teaches that this dispenser is digitally controlled. Liff discloses a data network scheme of networking multiple pharmaceutical dispensers. It would have been obvious at the time of the invention to have used Boyer's tablet dispenser in the system of Liff, as tablets are a recognized form of pharmaceutical which one ordinarily skilled in the art would want to provide to a system such as Liff's so as to dispense such drugs.

Again, Liff does not limit the pharmaceuticals it dispenses to packaged drugs, but also to broadly encompass any type of pharmaceutical dispenser one ordinarily skilled in the art would envision as being necessary to meet the needs of a typical healthcare system. Such a system would need capability to dispense bulk drugs, such as in tablet form. Additionally, such drug dispensing would need to be regulated as far as cost. Therefore, since Liff's system includes accounting and inventory algorithms, it would have been further recognizable to one ordinarily skilled to include bulk drug dispensers in Liff's system. The fact that Liff or any other of the cited prior art is for use with many patients, in a hospital or prison setting, or other setting is immaterial since these systems will still work the same as Applicant's claim limitations describe.

Regarding the recitation of an "individual patient" in the claims exemplified by Claim 22, the structure described by Liff, Boyer and Shusterman reads on Applicant's claims as described above, since the use of the system by an individual patient or a doctor does not change how the structure functions.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (571)272-6943. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald P. Walsh can be reached on (571)272-6944. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey A. Shapiro
Examiner
Art Unit 3653

January 5, 2006

GENE C. CRAWFORD
SUPERVISORY PATENT EXAMINER